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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,644	03/18/2005	Young Chul Sung	428.1049	2017
20311 7590 06/17/2009 LUCAS & MERCANTI, LLP 475 PARK AVENUE SOUTH 15TH FLOOR NEW YORK, NY 10016				
EXAMINER				
BOESEN, AGNIESZKA				
ART UNIT		PAPER NUMBER		
1648				
NOTIFICATION DATE		DELIVERY MODE		
06/17/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

info@lmiplaw.com

Office Action Summary

Application No.

10/528,644

Applicant(s)

SUNG ET AL.

Examiner

AGNIESZKA BOESEN

Art Unit

1648

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 5-17, 20-35 and 38-40 is/are pending in the application.
- 4a) Of the above claim(s) 30-35 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-17, 20-29, 38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The Amendment filed May 8, 2009 in response to the Office Action of December 8, 2008 is acknowledged and has been entered. Upon further consideration the finality of the Office action on December 8, 2008 is withdrawn and the prosecution is hereby REOPENED to make the following rejections. Any inconvenience is regretted.

Claims 1, 2, 5, 6, 8-17, 20-35 and 38-40 have been amended. Claims 30-35 and 40 are withdrawn. Claims 1, 2, 5-17, 20-29, 38 and 39 are under examination.

Claim Rejections - 35 USC § 112

Rejection of claims 1, 2, 4-17, 19-29, 38 and 39 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement **is withdrawn** in view of Applicant's amendment.

New Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-15, 22-29, 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "a base sequence represented by SEQ ID NO:" It is not clear what is the meaning of the phrase "a base sequence represented by SEQ ID NO:" Does the plasmid contain the recited SEQ ID NOS or does the plasmid contain a different sequence than the recited SEQ ID NOS? Correction and clarification is required.

Claims 38 and 39 recite the limitation "DNA vaccine" and "adenovirus vaccine". There is insufficient antecedent basis for this limitation in the claim. Correction is required.

Claim Rejections - 35 USC § 102

Rejection of claims 1, 2, 6, 16, 21 and new claims 38 and 39 under 35 U.S.C. 102(b) as being anticipated by Saito et al. (US Patent 5,731,172) **is withdrawn** in view of Applicant's amendment.

Rejection of claims 1, 2, 6 and new claim 38 under 35 U.S.C. 102(e) as being anticipated by Tang et al. (US 2004/0166488 A1) **is withdrawn** in view of Applicant's amendment.

New Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5, 6, 16, 17, 20, 21, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saito et al. (US Patent 5,731,172) in alternative over Tang et al. (US 2004/0166488 A1) in view of Lee et al. (Virology, 2001, Vol. 279, p. 271-279).

Saito et al. teaches a recombinant adenovirus vaccine comprising plasmids expressing the HCV genes (see Example 2). Although Saito et al. does not specifically disclose which HCV genes are expressed by the recombinant adenovirus, because Saito et al. broadly speaks about the

whole HCV genome, it is expected that all HCV genes, including E1, E2, NS3, NS4, and NS5 are present in Saito's recombinant adenoviral vaccine.

Tang et al. teaches a vaccine composition comprising a complete HCV genome comprising E1, E2, NS3, NS4, and NS5 genes of HCV (see [0007], [0024], [0034-0039], and claims 1-3). With regard to the limitations drawn to the size of the plasmids, the size of the particular genes comprised within the vaccine disclosed by Tang et al. is expected to range from 2 to 4 kb, because the HCV genes of the current invention and HCV genes disclosed by Tang et al. have identical structure. Although some variations may exist in different strains of the HCV virus with respect to the particular nucleic acids and certain positions, the length and thus the size of the genes remain the same.

Neither Tang nor Saito teach 35-40 amino acids eliminated from the N-terminal region of the core protein.

Lee teaches that the HCV core protein has immunosuppressive properties and suppresses the induction of the cytotoxic T cell response through inhibition of IFN-gamma, IL-2, IL-12 and NO production (see Results on pages 272-275 and Figure 2). Lee teaches that regardless of the expression level of the HCV core protein, either the expression level was high, medium or low, as long as the HCV core was truncated, the HCV core expressing cells suppressed the production of IL-12 and NO as compared to no IL-12 or NO inhibition by cells that did not express the HCV core (see Figure 2).

It would have been *prima facie* obvious to provide Saito's or Tang's composition comprising HCV genome comprising E1, E2, NS3, NS4, and NS5 genes of HCV and to eliminate the 35-40 amino acids of the N-terminal region of the HCV core protein.

One would have been motivated to remove 35-40 amino acids of the N-terminal region of the HCV core protein because Lee teaches that HCV core protein has immunosuppressive properties and suppresses the induction of the cytotoxic T cell response through inhibition of IFN-gamma, IL-2, IL-12 and NO production (see Results on pages 272-275 and Figure 2). Because Tang's and Saito's immunogenic composition is intended to induce the immune responses, in view of the teachings of Lee, the skilled artisan would have been motivated to remove the immunosuppressive HCV core.

Thus the present invention would have been *prima facie* obvious to the skilled artisan at the time the invention was made.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AGNIESZKA BOESEN whose telephone number is (571)272-8035. The examiner can normally be reached on 9:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen/

Examiner, Art Unit 1648